



258/299
Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
GINN, Richard S., et al.

Serial No.: 09/738,431

Filed: December 14, 2000

For: DEVICES FOR SEALING OPENINGS
THROUGH TISSUE AND APPARATUS
AND METHODS FOR DELIVERING
THEM

Group Art Unit: 3731

Examiner: Not yet assigned

RECEIVED
MAY 24 2001
TECHNICAL SERVICES UNIT 3100

Box Fee
Commissioner for Patents
Washington, DC 20231

PRELIMINARY AMENDMENT

Dear Sir/Madam:

Before calculation of claim fees and examination, please amend the above-identified application as follows:

IN THE CLAIMS:

Please cancel claims 1-38 without prejudice, and add the following new claims 39-81:

39. (new) An apparatus for sealing a passage through tissue, comprising:

an elongate shaft having a proximal end and a distal end; and

CERTIFICATE OF MAILING
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

May 17, 2001
Date of Deposit

Sally Hartwell
Sally Hartwell

05/23/2001 SHINASS1 00000054 09738431
45.00 OP
80.00 OP
02 F120E

a plug member disposed on the distal end of the elongate shaft, the plug member comprising a helical thread on its outer surface, the elongate shaft having a cross-section that is substantially smaller than a cross-section of the plug member.

40. (new) The apparatus of claim 39, wherein the plug member is at least partially tapered at its distal end.

41. (new) The apparatus of claim 39, wherein the plug member comprises a cavity in its distal end.

42. (new) The apparatus of claim 41, further comprising at least one of a hemostasis-promoting material and an infection-resistant material is disposed in the cavity.

43. (new) The apparatus of claim 42, wherein the material comprises intestinal submucosa.

44. (new) The apparatus of claim 39, further comprising at least one of a hemostasis-promoting material and an infection-resistant material secured to a distal end of the plug member.

45. (new) The apparatus of claim 39, wherein the plug member is releasable from the elongate shaft.

46. (new) The apparatus of claim 45, wherein the elongate shaft comprises an actuator for releasing the plug member from the distal end of the elongate shaft.

47. (new) The apparatus of claim 45, further comprising cooperating connectors on the distal end of the elongate shaft and on the plug member for releasably securing the plug member to the distal end of the elongate shaft.

48. (new) The apparatus of claim 45, wherein the plug member comprises an interior cavity, and wherein the elongate shaft comprises an engagement element extending from the distal end thereof for insertion into the cavity, the engagement element being expandable and collapsible for engaging and disengaging an interior wall of the plug member, thereby selectively securing the plug member to and releasing the plug member from the distal end of the elongate shaft, respectively.

49. (new) The apparatus of claim 48, wherein the engagement element comprises a mechanically expandable frame.

50. (new) The apparatus of claim 48, wherein the engagement element comprises an inflatable member.

51. (new) The apparatus of claim 48, wherein the plug member is sufficiently rigid such that the plug member is substantially self-supporting when the engagement member is collapsed.

52. (new) The apparatus of claim 45, wherein the plug member comprises bioabsorbable material.

53. (new) The apparatus of claim 39, wherein the plug member is substantially permanently attached to the distal end of the elongate shaft.

54. (new) The apparatus of claim 39, further comprising a lumen extending from the proximal end of the elongate shaft through the plug member, and a seal for selectively sealing the lumen.

55. (new) The apparatus of claim 54, wherein the seal is disposed on the proximal end of the elongate shaft.

56. (new) A device for sealing a passage through tissue, comprising a plug member formed from a bioabsorbable material, the plug member comprising a proximal end, a substantially closed distal end, and a helical thread on an outer cylindrical surface extending at least partially between the proximal and distal ends.

57. (new) The device of claim 56, wherein the plug member is at least partially tapered towards the distal end.

58. (new) The device of claim 56, further comprising a connector on the proximal end for detachably securing the plug member to a delivery apparatus.

59. (new) The device of claim 56, wherein the body further comprises an internal cavity communicating with an opening in the proximal end.

60. (new) An apparatus for sealing a passage through tissue, comprising:
an elongate shaft having a proximal end and a distal end; and
a plug member substantially permanently attached to the distal end of the elongate shaft,
the plug member comprising a helical thread on its outer surface.

61. (new) The apparatus of claim 60, wherein the plug member is at least partially tapered at its distal end.

62. (new) The apparatus of claim 60, wherein the plug member comprises a cavity in its distal end.

63. (new) The apparatus of claim 62, further comprising at least one of a hemostasis-promoting material and an infection-resistant material disposed in the cavity.

64. (new) The apparatus of claim 63, wherein the material comprises intestinal submucosa.

65. (new) The apparatus of claim 60, further comprising at least one of a hemostasis-promoting material and an infection-resistant material secured to a distal end of the plug member.

66. (new) The apparatus of claim 60, wherein the plug member comprises bioabsorbable material.

67. (new) The apparatus of claim 60, further comprising a lumen extending from the proximal end of the elongate shaft through the plug member, and a seal for selectively sealing the lumen.

68. (new) The apparatus of claim 67, wherein the seal is disposed on the proximal end of the elongate shaft.

69. (new) A method for sealing a passage through tissue, comprising:
providing an apparatus comprising an elongate shaft and a plug member disposed on a distal end of the elongate shaft, the plug member comprising an outer surface including a helical thread;

inserting a distal end of the plug member into the passage until the helical thread begins to contact tissue surrounding passage; and

rotating the elongate shaft, thereby threading the plug member into the passage, the plug member engaging the tissue to substantially seal the passage.

70. (new) The method of claim 69, wherein the passage communicates with a blood vessel within the tissue, and wherein the elongate shaft is rotated until the plug member substantially seals a wall of the blood vessel.

71. (new) The method of claim 69, wherein the plug member is left within the passage for sufficient time for hemostasis to occur.

72. (new) The method of claim 71, further comprising removing the plug member from the passage.

73. (new) The method of claim 72, wherein a hemostasis-promoting material is provided on a distal end of the plug member, and wherein the material is left in the passage when the plug member is removed.

74. (new) The method of claim 69, wherein the elongate shaft is rotated until it engages a blood vessel within the tissue, and wherein the method further comprises:

- monitoring blood flow through the blood vessel;
- rotating the elongate shaft to thread the plug member into the passage until blood flow substantially ceases through the blood vessel; and
- reversing rotation of the elongate shaft to back the plug member a predetermined distance, thereby allowing blood flow to resume through the blood vessel.

75. (new) The method of claim 69, further comprising releasing the plug member from the elongate shaft within the passage.

76. (new) The method of claim 75, wherein the plug member comprises a bioabsorbable material, and wherein the method further comprises leaving the plug member within the passage until it is absorbed by the tissue.

77. (new) The method of claim 69, wherein the elongate shaft includes a lumen extending from its proximal end through the plug member.

78. (new) The method of claim 77, further comprising monitoring fluid flow from a distal end of the plug member through the lumen.

79. (new) The method of claim 69, further comprising introducing one or more instruments through the passage to perform a procedure before inserting the plug member into the passage.

80. (new) An apparatus for sealing a passage through tissue, comprising:
an elongate member having a proximal end and a distal end, the distal end having a connector thereon; and

a plug member releasably secured to the distal end of the elongate member by the connector, the plug member comprising a helical thread on its outer surface, the elongate member having a cross-section that is substantially smaller than a cross-section of the plug member.

81. (new) A method for sealing a passage through tissue, comprising:
providing an apparatus comprising an elongate shaft and a plug member disposed on a distal end of the elongate shaft, the plug member comprising an outer surface including a helical thread;
inserting a distal end of the plug member into the passage;
rotating the elongate shaft, thereby threading the plug member into the passage, the plug member engaging the tissue to substantially seal the passage; and
reversing rotation of the elongate shaft to back the plug member a predetermined distance away from the blood vessel.

REMARKS:

Before calculation of claim fees and before examination, Applicants request consideration of the present amendment.

Respectfully submitted,

LYON & LYON LLP

Dated: May 17, 2001

By



William A. English
Reg. No. 42,515
Attorneys for Applicants

633 West Fifth Street
Suite 4700
Los Angeles, CA 90071-2066
(949) 567-2300